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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/648,416

08/25/2003

Sung Kee Jo

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4031

34704 7590 12/16/2004
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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/648,416

Applicant(s)

JO ET AL.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0803 & 0904</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claims 1-10 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9 are rendered vague and indefinite because they fail to recite any operative amounts of the claimed first hot water extract and the claimed polysaccharide fraction, each to the other, within the claimed herbal composition. Therefore, it is unclear if each of the claimed ingredients is an active agent within the claimed composition, if one of the ingredients is merely some type of inert agent, and/or if it is present in very small amounts representing perhaps a contaminant or residue. Based upon the instant teachings which disclose that the combination of both of the claimed ingredients are necessary so as to provide enhanced therapeutic activities with respect to the claimed/disclosed clinical conditions, each of the claimed therapeutically effective ingredients (the first hot water extract and the polysaccharide fraction obtained from the second hot water extract) is deemed to be an essential element of the invention and, as such, they should be clearly defined (e.g., functionally) in the claim language itself.

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Accordingly, it is suggested that in claim 1, the phrase --an effective amount of-- be inserted before the phrase "a first hot water extract" (line 3) and before the phrase "a polysaccharide fraction" (line 6); and that in claim 10, the phrase --an effective amount of-- be inserted before the phrase "the polysaccharide fraction" (line 13) and before the phrase "the hot-water extract" (line 14) - or alternatively that claims 1 and 9 be amended so as to recite particular disclosed amount ranges and/or ratios of these two essential ingredients within the claimed composition (and its method of preparation) - to clarify this ambiguity.

Claim 2 recites the limitation "the polysaccharide fraction in the first hot-water extract" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim (please note that the first hot-water extract of claim 1 is not defined as having polysaccharide therein).

Claim 9 recites the limitation "the mixture" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the range" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 is rendered vague and indefinite by the linking term "preferably" (line 3). A broad range or limitation followed by linking terms (for example, preferably, maybe, for instance, especially) and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired (see MPEP 2173.05(c) for additional information).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

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The claims are free of the art. The closest prior art is that of Korean Patent No. KR 2001-100551 (KR Appl. No. 2000-23772) which teaches hot-water extracts of the instantly claimed ingredients having immunological, hematopoiesis, and radiation protection activity. However, the prior art of record does not teach or reasonably disclose the instantly claimed invention. As instantly disclosed and demonstrated, the claimed herbal composition (comprising the claimed first hot water herbal extract and the claimed polysaccharide fraction precipitated from the second hot water herbal extract) provides enhanced therapeutic activities in comparison to the hot water herbal extract composition of KR 2001-100551 (see, e.g., page 6, line 2 - page 7, line 4 of the instant specification, as well as the Examples and Figures therein).

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
Art Unit 1654